102. The pharmaceutical composition of claim 50, wherein the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.--

REMARKS

INTRODUCTORY COMMENTS:

In the Office Action under reply, pending claims 1-12 and 37-51 were examined, claims 13-36 having been withdrawn as a result of restriction. The claims were rejected as follows: under 35 U.S.C. §112, second paragraph (claim 51); under 35 U.S.C. §102(b) as anticipated by Edgar et al. (claims 1-4, 37, 41-44 and 51); and under 35 U.S.C. §103(a) as obvious over Edgar et al. in view of Patel et al. (claims 5-12, 38-40 and 45-50). Claims 37-49 and 51 were also objected to as being dependent upon non-elected claims 13-36.

The foregoing objections and rejections are addressed in part by the above amendments and in part by the comments that follow. With the above amendments, claims 2 and 13-36 have been canceled, claims 1, 3, 5, 8, 10, 37-43, and 46-51 have been amended, and new claims 52-102 have been added. Thus, claims 1, 3-12, and 37-102 are now pending.

For the Examiner's convenience, the pending claims upon entry of this amendment are set forth in Appendix B.

THE AMENDMENTS TO THE CLAIMS:

Claim 1 has been amended to recite that the solubilizer comprises a vitamin E substance and further that the ratio of the fenofibrate to the solubilizer is less than or equal to 0.305. Support for the amendment can be found within the application as filed, and, in particular, in Examples 24-30 and 32-34. These Examples show a ratio of fenofibrate to the vitamin E substance of 0.305 or less. The table below shows the ratio calculations for each of these examples.

Calculated Ratios of Fenofibrate to vitamin E substance(s) in Selected Examples

A	B	C	D	E
Example	Amount (mg) of fenofibrate in the composition*	Amount (mg) of vitamin E substance(s) in the composition*	Amount (IU)† of vitamin E substance(s) in the composition*	Ratio‡ of fenofibrate (mg) to vitamin E substance(s) (IU)
24	200	dl-α-tocopherol = 1000	total = 1100	0.182
25	40	dl-α-tocopherol = 600 vitamin E-TPGS = 200	660 77.4 total = 737.4	0.0542
26	67	dl-α-tocopherol = 600 vitamin E-TPGS = 300	660 116.1 total = 776.1	0.086
27	67	dl-α-tocopherol = 400 vitamin E-TPGS = 200	440 77.4 total = 517.4	0.129
28	67	dl-α-tocopherol = 400	total = 440	0.152
29	67	dl-α-tocopherol = 500	total = 550	0.122
30	67	dl-α-tocopherol = 200	total = 220	0.305
32	67	dl-α-tocopherol = 400	total = 440	0.152
33	67	d-α-tocopherol acetate = 500	total = 680	0.099
34	67	d-α-tocopherol acetate = 500	total = 680	0.099

* Note that other components may be present in the composition.
† To obtain IU units, multiply the mg amount of the vitamin E substance in column C by the appropriate conversion factor: 1.1 IU for each 1 mg of dl-α-tocopherol; 0.387 IU for each 1 mg of vitamin E-TPGS; and 1.36 IU for each 1 mg of d-α-tocopherol acetate. See USP 24-NF 19, March 2001.
‡ To obtain the ratio, divide column B by the total provided in column D.

The ratio of fenofibrate (mg) to the vitamin E substance (IU) in Example 30 is 0.305. The ratios of Examples 24-29 and 32-33 are each less than 0.305. Thus, the application as filed supports compositions in which the ratio of fenofibrate to a solubilizer comprised of a vitamin E substance is less than or equal to 0.305.

Claim 50 has been amended to specify that the hydrophobic drug is one that has not been micronized, or that has been micronized in the absence of a solid surfactant. This amendment is supported in the specification on page 12, lines 22-28, on page 16, lines 7-10, and elsewhere.

Claim 51 has also been amended to clarify that the composition is to treat a patient suffering from a fenofibrate-responsive condition, disease or disorder. The new claim is supported by the specification on page 23, lines 19-22.

The remainder of the claim amendments do not materially affect the substance of the claims, and are entirely supported by the original disclosure.

The new claims are as follows.

New claim 52 is directed to a ratio of fenofibrate to solubilizer of less than or equal to 0.182. See the above table for support. That is, Example 24 provides support for a ratio of 0.182, while Examples 25-29 and 32-34 support ratios of less than 0.182.

New claims 53, 60 and 88 specify the therapeutically effective amount of fenofibrate in the dosage form as a "unit dosage," which is supported on page 20, lines 11-12.

New claim 69 recites that the hydrophobic drug is selected from fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant. This claim is supported in the specification on page 12, lines 22-28, on page 16, lines 7-10, and elsewhere.

New claims 97-100 recite fenofibrate-responsive conditions, diseases, or disorders as now specified in claim 51 as amended. The specific conditions, diseases and disorders recited in these new claims may be found in the specification on pages 9-10, bridging paragraph.

New claims 101 and 102 are analogous to claim 50, but specify the ratio of the hydrophobic drug to the vitamin E substance as less than or equal to 0.305 mg/IU. See the above table and discussion pertaining to the amendment of claim 1.

The remaining new claims parallel the originally filed claims, but depend from new independent claims 54 and 69. Accordingly, these new claims are fully supported by the original disclosure as well.

THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION:

Claim 51 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Specifically, the Examiner has taken the position that the phrase "treating a patient who would benefit from..." is vague and indefinite as allegedly not being clear as to scope. The Examiner questions whether applicants mean treating any condition, disease or

disorder as described in the specification or whether applicants intend the treatment of specific lipid disorders.

While not wishing to acquiesce in the rejection, applicants have amended the claim to specify that the patient is suffering from a fenofibrate-responsive condition, disease or disorder, as explained in the specification on page 23, at lines 16-23. Applicants submit that as one of ordinary skill in the art, e.g., a physician or other medical professional, will recognize fenofibrate-responsive conditions, diseases and disorders, particularly when the claim is read in light of the disclosure in the patent application concerning such indications, the claim cannot be considered vague or indefinite. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

THE 35 U.S.C. §102(B) REJECTION OVER EDGAR ET AL.:

The Examiner has rejected claims 1-4, 37, 41-44 and 51 as anticipated by Edgar et al., citing the reference as teaching a synergistic combination of 33-200 mg of fenofibrate and 100-600 mg of a vitamin E substance solution, in the form of a gelatin capsule, for treating and preventing pathological conditions including atheromatous disease, diabetes, arterial hypertension and restenosis. The Examiner also states that recitations of an inherent property of a previously disclosed component, such as the solubilizing capability of a known vitamin E substance, does not limit composition claims. Applicants respectfully submit that the reference does not disclose each and every element of the invention as recited in the currently pending claims.

It is axiomatic that in order to demonstrate anticipation, all elements of a claimed invention must be disclosed in a single prior art reference. *In re Bond*, 15 U.S.P.Q. 2d 1566, 1567 (Fed. Cir. 1990).

The reference does not describe compositions comprising fenofibrate and a solubilizer comprising a vitamin E substance wherein the ratio of the fenofibrate to the solubilizer is less than or equal to 0.305 mg/IU. Although Edgar et al. describes compositions comprising a fenofibrate/vitamin E substance combination, the ratio of the fenofibrate to the vitamin E substance is between 0.33 and 2 mg/IU. The criticality of this ratio is repeated throughout the

patent. See, for example: the abstract of the disclosure; column 3, lines 5-14; column 3, lines 26-28; column 4, lines 2-10; column 4, lines 25-30; column 5, lines 49-57; and the Examples. Edgar et al. does not disclose compositions containing fenofibrate and a vitamin E substance outside the 0.33 to 2 mg/IU range as the described ratio "is *always* between 0.33 and 2 mg/IU." See column 4, line 30 [emphasis added]. As all of the elements of the claimed invention (particularly compositions comprising fenofibrate and a solubilizer at a ratio less than or equal to 0.305 mg/IU) are not disclosed in Edgar et al., the reference cannot anticipate the pending claims.

The new claims are also novel over Edgar et al., as the reference does not describe compositions containing fenofibrate and a solubilizer comprising a trialkyl citrate, a lactone, a nitrogen-containing solvent or a combination thereof, nor are compositions disclosed wherein the fenofibrate is not micronized, or is micronized, but in the absence of a solid surfactant. As pointed out in the Background section of the patent application, and as emphasized throughout, preparation of micronized fenofibrate, or co-micronizing fenofibrate with a solid surfactant, is a time consuming and costly process. Furthermore, micronized microparticles, or co-micronized mixtures containing fenofibrate, require complete and consistent dissolution of the drug as a prerequisite for the effective absorption of fenofibrate, and to obtain a satisfactory bioavailability profile. With applicants' claimed compositions, micronization is unnecessary.

Accordingly, reconsideration and withdrawal of the 35 U.S.C. §102(b) rejection over Edgar et al. is respectfully requested.

THE 35 U.S.C. §103(A) REJECTION OVER EDGAR ET AL. IN VIEW OF PATEL ET AL.:

The Examiner rejected claims 5-12, 38-40 and 45-50 under 35 U.S.C. §103(a) as obvious over Edgar et al. in view of Patel et al.

In response, applicants point out that the inventors on the Patel et al. patent are the same as the inventors on the present application, and that both applications are commonly owned and have always been subject to an obligation of common ownership. As a consequence, Patel et al. does not qualify as prior art under 35 U.S.C. §102(e) because the invention therein is not that "of another," nor can the patent be used in a rejection under 35 U.S.C. §103(a).

Applicants respectfully submit that the Edgar et al. reference alone does not support a rejection under 35 U.S.C. §103, insofar as there is no suggestion or motivation to modify the reference's teaching to substantially increase the ratio of fenofibrate to solubilizer, or to forego co-micronization with a solid surfactant. Edgar et al. uses both fenofibrate and the vitamin E substance as antioxidants to protect plasma lipoproteins, particularly low density lipoproteins (LDLs), from oxidation. The ratio of fenofibrate to vitamin E substance, and the co-micronization of the fenofibrate with a solid surfactant, are stated as required to achieve the purpose of the invention, increasing the capability of both the vitamin E substance and the fenofibrate as antioxidants. See column 3, lines 5-13.

Furthermore, Edgar et al. explicitly teaches away from fenofibrate/vitamin E substance combinations in which the fenofibrate/vitamin E substance ratio is outside of the 0.33 to 2 mg/IU range, and in which the fenofibrate has not been co-micronized with a solid surfactant. See, for example, column 2, line 65 to column 3, line 13, where the disclosed compositions are contrasted with compositions containing fenofibrate that has not been micronized, and the patentee states that the synergistic antioxidant effect can be obtained only when the fenofibrate is co-micronized with a solid surfactant and when the fenofibrate/vitamin E substance ratio is in the range of 0.33 to 2 mg/IU.

Without *a priori* knowledge of applicants' invention, then, wherein it has now been discovered that a vitamin E substance acts as a solubilizer for fenofibrate when the fenofibrate/vitamin E substance ratio is below about 0.305 mg/IU, and wherein the fenofibrate is not co-micronized with a solid surfactant (and may not be micronized at all), one would not be motivated to modify the Edgar et al. reference to arrive at applicants' claimed compositions. It is well settled in the law that such a "hindsight" analysis is improper in the context of an obviousness determination. Accordingly, a rejection under 35 U.S.C. §103 could not be maintained.

CONCLUSION

In sum, it is submitted that the claims satisfy the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, the application should now be in

condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

If the Examiner has any questions or wishes to discuss the matter further he may contact the undersigned at (650) 330-0900. Please note that this is a new telephone number, and that all future correspondence concerning this application should be directed to our new address, below.

Respectfully submitted,

DRAFT

By: _____
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_____
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APPENDIX A

REDACTED CLAIMS INDICATING AMENDMENTS MADE

IN THE CLAIMS:

Cancel claim 2 without prejudice.

Please amend claims 1, 3, 5, 8, 10, 37-43 and 46-51 as follows:

1. (Amended) A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of fenofibrate; and

b) a solubilizer comprising a vitamin E substance, ~~a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof~~ wherein the ratio of the fenofibrate to the vitamin E substance is less than or equal to 0.305 mg/IU.

3. (Amended) The pharmaceutical composition of claim ~~2~~ 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

5. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a trialkyl citrate.

8. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a lactone.

10. (Amended) The pharmaceutical composition of claim ~~1~~ 54, wherein said solubilizer is a nitrogen-containing solvent.

37. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, in a liquid form.

38. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, in a semi-liquid form.

39. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, wherein the fenofibrate is at least 50% solubilized in said composition.

40. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 39, wherein the fenofibrate is at least 75% solubilized in said composition.

41. (Amended) A pharmaceutical dosage form comprising the pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1.

42. (Amended) The pharmaceutical dosage form of claim ~~41~~ 54, wherein the unit dosage of fenofibrate is ~~present in an amount of~~ from about 40 mg to about 250 mg.

43. (Amended) The pharmaceutical dosage form of claim ~~41~~ 54, wherein the unit dosage of fenofibrate is ~~present in an amount of~~ from about ~~40~~ 67 mg to about ~~250~~ 200 mg.

46. (Amended) The pharmaceutical composition of ~~any one of claims 1, 13, 15, 21, 24, 26, 31 or 36~~ claim 1, wherein the fenofibrate is completely solubilized in said composition.

47. (Amended) The pharmaceutical dosage form of claim ~~41, wherein fenofibrate is solubilized in an amount of at least about 40 mg~~ 42, wherein at least about 40 mg of the fenofibrate is solubilized.

48. (Amended) The pharmaceutical dosage form of claim ~~42, wherein fenofibrate is solubilized in an amount of at least about 67 mg~~ 43, wherein at least about 67 mg of the fenofibrate is solubilized.

49. (Amended) The pharmaceutical dosage form of claim ~~42, wherein fenofibrate is solubilized in an amount of at least about 100 mg~~ 48, wherein at least about 100 mg of the fenofibrate is solubilized.

50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, ~~and wherein~~ the vitamin E substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have not been micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

51. (Amended) A method for treating a patient ~~who would benefit from administration of a fenofibrate-containing composition~~ suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically ~~acceptable~~ effective amount of the pharmaceutical composition of any one of claims 1, ~~13, 15, 21, 24, 26, 31 or 36~~54 or 69.

Also add the following new claims 52-102:

--52. The pharmaceutical composition of claim 1, wherein the ratio of the fenofibrate to the solubilizer is less than or equal to 0.182 mg/IU.

53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

55. The pharmaceutical composition of claim 54, in a liquid form.

56. The pharmaceutical composition of claim 54, in a semi-liquid form.

57. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in said composition.

58. The pharmaceutical composition of claim 57, wherein the fenofibrate is at least 75% solubilized in said composition.

59. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

60. The pharmaceutical dosage form of claim 59, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

61. The pharmaceutical dosage form of claim 60, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

62. The pharmaceutical dosage form of claim 61, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

63. The pharmaceutical dosage form of claim 59, in capsule form.

64. The pharmaceutical dosage form of claim 59, in the form of a drink.

65. The pharmaceutical composition of claim 54, wherein the fenofibrate is completely solubilized in said composition.

66. The pharmaceutical dosage form of claim 61, wherein at least about 40 mg of the fenofibrate is solubilized.

67. The pharmaceutical dosage form of claim 62, wherein at least about 67 mg of the fenofibrate is solubilized.

68. The pharmaceutical dosage form of claim 63, wherein at least about 100 mg of the fenofibrate is solubilized.

69. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and

b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and

c) an optional solid surfactant.

70. The pharmaceutical composition of claim 69, wherein the fenofibrate has not been micronized.

71. The pharmaceutical composition of claim 69, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

72. The pharmaceutical composition of claim 69, wherein said solubilizer is a vitamin E substance.

73. The pharmaceutical composition of claim 72, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein said vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

75. The pharmaceutical composition of claim 74, wherein said solubilizer is a trialkyl citrate.

76. The pharmaceutical composition of claim 75, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

77. The pharmaceutical composition of claim 76, wherein said trialkyl citrate is triethyl citrate.

78. The pharmaceutical composition of claim 69, wherein said solubilizer is a lactone.

79. The pharmaceutical composition of claim 78, wherein said lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

80. The pharmaceutical composition of claim 69, wherein said solubilizer is a nitrogen-containing solvent.

81. The pharmaceutical composition of claim 80, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

82. The pharmaceutical composition of claim 81, wherein said solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

83. The pharmaceutical composition of claim 69, in a liquid form.

84. The pharmaceutical composition of claim 69, in a semi-liquid form.

85. The pharmaceutical composition of claim 69, wherein the fenofibrate is at least 50% solubilized in said composition.

86. The pharmaceutical composition of claim 85, wherein the fenofibrate is at least 75% solubilized in said composition.

87. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 71.

88. The pharmaceutical dosage form of claim 86, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

89. The pharmaceutical dosage form of claim 88, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

90. The pharmaceutical dosage form of claim 89, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

91. The pharmaceutical dosage form of claim 87, in capsule form.

92. The pharmaceutical dosage form of claim 87, in the form of a drink.

93. The pharmaceutical composition of claim 69, wherein the fenofibrate is completely solubilized in said composition.

94. The pharmaceutical dosage form of claim 89, wherein at least about 40 mg of the fenofibrate is solubilized.

95. The pharmaceutical dosage form of claim 90, wherein at least about 67 mg of the fenofibrate is solubilized.

96. The pharmaceutical dosage form of claim 95, wherein at least about 100 mg of the fenofibrate is solubilized.

97. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

98. The method of claim 97, wherein the lipid disorder is an above-normal level of cholesterol.

99. The method of claim 97, wherein the lipid disorder is an above-normal triglyceride level.

100. The method of claim 97, wherein the lipid disorder is a below-normal level of high density lipoproteins.

101. A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, and the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.

102. The pharmaceutical composition of claim 50, wherein the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.--

APPENDIX B

PENDING CLAIMS UPON ENTRY OF THE AMENDMENTS

1. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of fenofibrate; and

b) a solubilizer comprising a vitamin E substance, wherein the ratio of the fenofibrate to the vitamin E substance is less than or equal to 0.305 mg/IU.

3. The pharmaceutical composition of claim 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

4. The pharmaceutical composition of claim 3, wherein said vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

5. The pharmaceutical composition of claim 54, wherein said solubilizer is a trialkyl citrate.

6. The pharmaceutical composition of claim 5, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

7. The pharmaceutical composition of claim 6, wherein said trialkyl citrate is triethyl citrate.

8. The pharmaceutical composition of claim 54, wherein said solubilizer is a lactone.

9. The pharmaceutical composition of claim 8, wherein said lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

10. The pharmaceutical composition of claim 54, wherein said solubilizer is a nitrogen-containing solvent.

11. The pharmaceutical composition of claim 10, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

12. The pharmaceutical composition of claim 10, wherein said solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

37. The pharmaceutical composition of claim 1, in a liquid form.

38. The pharmaceutical composition of claim 1, in a semi-liquid form.

39. The pharmaceutical composition of claim 1, wherein the fenofibrate is at least 50% solubilized in said composition.

40. The pharmaceutical composition of claim 39, wherein the fenofibrate is at least 75% solubilized in said composition.

41. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 1.

42. The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

43. The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

44. The pharmaceutical dosage form of claim 41, in capsule form.

45. The pharmaceutical dosage form of claim 41, in the form of a drink.

46. The pharmaceutical composition of claim 1, wherein the fenofibrate is completely solubilized in said composition.

47. The pharmaceutical dosage form of claim 42, wherein at least about 40 mg of the fenofibrate is solubilized.

48. The pharmaceutical dosage form of claim 43, wherein at least about 67 mg of the fenofibrate is solubilized.

49. The pharmaceutical dosage form of claim 48, wherein at least about 100 mg of the fenofibrate is solubilized.

50. A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, the vitamin E

substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have not been micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

51. A method for treating a patient suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically effective amount of any one of claims 1, 54 or 69.

52. The pharmaceutical composition of claim 1, wherein the ratio of the fenofibrate to the solubilizer is less than or equal to 0.182 mg/IU.

53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

a) a therapeutically effective amount of fenofibrate; and

b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

55. The pharmaceutical composition of claim 54, in a liquid form.

56. The pharmaceutical composition of claim 54, in a semi-liquid form.

57. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in said composition.

58. The pharmaceutical composition of claim 57, wherein the fenofibrate is at least 75% solubilized in said composition.

59. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

60. The pharmaceutical dosage form of claim 59, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

61. The pharmaceutical dosage form of claim 60, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

62. The pharmaceutical dosage form of claim 61, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

63. The pharmaceutical dosage form of claim 59, in capsule form.

64. The pharmaceutical dosage form of claim 59, in the form of a drink.

65. The pharmaceutical composition of claim 54, wherein the fenofibrate is completely solubilized in said composition.

66. The pharmaceutical dosage form of claim 61, wherein at least about 40 mg of the fenofibrate is solubilized.

67. The pharmaceutical dosage form of claim 62, wherein at least about 67 mg of the fenofibrate is solubilized.

68. The pharmaceutical dosage form of claim 63, wherein at least about 100 mg of the fenofibrate is solubilized.

69. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and

b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and

c) an optional solid surfactant.

70. The pharmaceutical composition of claim 69, wherein the fenofibrate has not been micronized.

71. The pharmaceutical composition of claim 69, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

72. The pharmaceutical composition of claim 69, wherein said solubilizer is a vitamin E substance.

73. The pharmaceutical composition of claim 72, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein said vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

75. The pharmaceutical composition of claim 74, wherein said solubilizer is a trialkyl citrate.

76. The pharmaceutical composition of claim 75, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

77. The pharmaceutical composition of claim 76, wherein said trialkyl citrate is triethyl citrate.

78. The pharmaceutical composition of claim 69, wherein said solubilizer is a lactone.

79. The pharmaceutical composition of claim 78, wherein said lactone is selected from the group consisting of ε-caprolactone and isomers thereof, δ-valerolactone and isomers thereof and β-butyrolactone and isomers thereof and mixtures thereof.

80. The pharmaceutical composition of claim 69, wherein said solubilizer is a nitrogen-containing solvent.

81. The pharmaceutical composition of claim 80, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

82. The pharmaceutical composition of claim 81, wherein said solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

83. The pharmaceutical composition of claim 69, in a liquid form.

84. The pharmaceutical composition of claim 69, in a semi-liquid form.

85. The pharmaceutical composition of claim 69, wherein the fenofibrate is at least 50% solubilized in said composition.

86. The pharmaceutical composition of claim 85, wherein the fenofibrate is at least 75% solubilized in said composition.

87. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 71.

88. The pharmaceutical dosage form of claim 86, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

89. The pharmaceutical dosage form of claim 88, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

90. The pharmaceutical dosage form of claim 89, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

91. The pharmaceutical dosage form of claim 87, in capsule form.

92. The pharmaceutical dosage form of claim 87, in the form of a drink.

93. The pharmaceutical composition of claim 69, wherein the fenofibrate is completely solubilized in said composition.

94. The pharmaceutical dosage form of claim 89, wherein at least about 40 mg of the fenofibrate is solubilized.

95. The pharmaceutical dosage form of claim 90, wherein at least about 67 mg of the fenofibrate is solubilized.

96. The pharmaceutical dosage form of claim 95, wherein at least about 100 mg of the fenofibrate is solubilized.

97. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

98. The method of claim 97, wherein the lipid disorder is an above-normal level of cholesterol.

99. The method of claim 97, wherein the lipid disorder is an above-normal triglyceride level.

100. The method of claim 97, wherein the lipid disorder is a below-normal level of high density lipoproteins.

101. A pharmaceutical composition for administration of a hydrophobic drug comprising:

(a) a therapeutically effective amount of a hydrophobic drug; and

(b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, and the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.

102. The pharmaceutical composition of claim 50, wherein the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.